

PSJ3  
Exhibit 213C



Effective Controls Against  
Diversion of Controlled  
Substances  
Meeting with  
Watson Pharmaceuticals  
August 23, 2007



# Effective Controls Against Diversion of Controlled Substances

Meeting with  
Watson Pharmaceuticals  
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## Internet Pharmacies

- Domestic Based
  - Related to an existing pharmacy
    - Walk in patients with prescriptions
    - Some legitimate some not
  - Unrelated to brick and mortar pharmacy
    - No local patients or doctors
    - No walk-in business
- Foreign based



## Involved With Internet Pharmacies

- Doctors
- Pharmacies
- Distributors
- Internet Service Providers
- Credit Card Companies
- Delivery Services
- Internet Pharmacy Facilitators

## ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor



## DEA DISTRIBUTOR REGISTRATIONS

- Title 21 United States Code, Section 823
  - Is the registration in the public interest?
    - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels

## Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
  - Mail order sales to doctor
  - Most sales were Morphine
  - Increase in quantities purchased
  - Business practices attracted customers who were violating the law
  - Drugs have inherent susceptibility to harmful and illegal use



## EZ RX, LLC

- 69 FR 63,178 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 300,000 dosage units in three months
    - Phentermine, Phendimetrazine, Ambien

## RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 19,300,000 dosage units of various controlled substances
    - Based on Internet Questionnaires
  - Not in the course of professional practice



## CRJ Pharmacy, Inc., & YPM Total Care Pharmacy, Inc.

- 72 FR 30,846 (2007)
  - Immediate Suspension Order
  - Revocation of Registration
    - Between Jan – Nov 2006, CRJ dispensed 1,416,320 d.u. of hydrocodone products.
    - Between May – Nov 2006, YPM dispensed 846,800 d.u. of hydrocodone products.
    - Prescriptions were filled based upon an on-line questionnaire.

## Southwood Pharmaceuticals, Inc.

- 72 FR 36,487 (2007)
  - Revocation of Registration
  - Immediate Suspension Order
    - Failure to maintain effective controls against diversion
    - Supplied millions of dosage units of controlled substances to Internet pharmacies
    - Failure to exercise due diligence (21 USC 823)